DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service d2027b

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

August 11, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 45

Ellis W. Abrahamson
President
Caleb Laboratories, Inc.
529 South Seventh Street, #288
Minneapolis, Minnesota 55415

Dear Mr. Abramson:

On July 21-22, 1998, the Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility in Minneapolis, MN. During that inspection our investigator observed and documented serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211).

The violations observed during our inspection include but are not limited to the following:

1. Failure to determine conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165). For example, parts of lots 1520 through 1523 have been shipped, yet the finished product analysis results have not been received from [redacted] the testing laboratory.

2. Failure to have a written testing program designed to assess the stability characteristics of drug products (21 CFR 211.166). For example, you have no stability testing program to support the two-year expiration date on Lycall Ointment.

3. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program (21 CFR 211.160). For example, you have not calibrated (a) the scale used to weigh raw components and (b) the thermometer used to determine temperature during production.

4. Failure to prepare for each batch of drug product produced batch production and control records. These records shall include complete information relating to the production and control of each batch (21 CFR 211.188). Your batch records are inadequate in that (a) the weights recorded do not represent the actual weighed amount and (b) lot 1525 was produced on July 17, 1998, yet the weighed amounts of raw components had not been recorded on the batch record as of July 22, 1998.

The violations of the Act described above are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with this statute. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the award of contracts.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within 10 working days of receiving this letter. Your response should describe the specific actions you will take, or have taken, to correct the noted violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within 10 working days, please state the reason for the delay and time within corrections will be completed.

We appreciate the corrective actions you have made over the years. However, a face-to-face meeting would be appropriate to discuss the on-going GMP problems at your facility. We have scheduled Monday, August 31, 1998 at 10:00 a.m. for a meeting at our District Office in Minneapolis, MN.

Your reply to this letter should be sent to Compliance Officer Carrie A. Hoffman at the above address. If the meeting time arranged above is a problem, please call Ms. Hoffman at (612) 334-4100 ext. 159 to make arrangements that are suitable for everyone.

Sincerely,

James A. Rahto
District Director
Minneapolis District

CAH/ccl